Section 5 - 510(k) Summary

JUL 2 4 2013

1. Submission Sponsor

LiNA Medical ApS
Formervangen 5
2600 Glostrup
Denmark
Phone: +45 4329 6666
Fax: +45 4329 6699
Contact: Louisa Memborg, Regulatory Affairs Officer

2. Submission Correspondent

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
Cell Phone: (406) 579-8124
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Richard Gillis, Ph.D., Senior Consultant
Email: project.management@emergogroup.com

3. Date Prepared

27 JAN 2013

4. Device Identification

Trade/Proprietary Name:	LiNA Bipolar Loop
Common/Usual Name:	Bipolar electrosurgical Loop
Classification Name:	Bipolar Endoscopic coagulator-cutter and accessories
Classification Regulation:	21 CFR 884.4150
Product Code:	HIN
Device Class:	Class II
Classification Panel:	Obstetrics and Gynecology Panel

5. Predicate Devices

1. LiNA Loop (K070315)
2. PKS BiLL (K111059)

6. Device Description

The LiNA Bipolar Loop is a 5 mm single use laparoscopic instrument. It is available with three different loop dimensions; 160mm x 80mm, 200mm x 100mm and 240mm x 120mm. The outer 15mm on each side of the loop is not insulated i.e. the bipolar cutting area length

totals 30mm. The device is single use ethylene oxide sterilized and is compatible with most standard electrosurgical generators that provide a bipolar outlet.

7. Intended Use

The LiNA Bipolar Loop is a 5mm bipolar electrosurgical device intended for amputating the mobilized uterus during laparoscopic supracervical hysterectomy and resection of devasculated subserosal pedunculated myomas. To be used with an electrosurgical generator that provides a bipolar outlet.

8. Comparison of Technological Characteristics

The following table compares the LiNA Bipolar Loop to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**LiNA Medical ApS** Formervangen 5 2600 Glostrup Denmark	**LiNA Medical ApS** Formervangen 5 2600 Glostrup Denmark	**Gyrus ACMI, Inc** 136 Turnpike Rd. Southborough, MA 01772-2104
Trade Name	LiNA Bipolar Loop	LiNA Loop	PKS BiLL
510(k) Number	TBD	K070315	K111059
Product Code	HIN	KNF	HIN
Regulation Number	21 CFR 884.4150	21 CFR 884.4160	21 CFR 884.4150
Regulation Name	Bipolar endoscopic coagulator-cutter and accessories	Coagulator-cutter, endoscopic, unipolar (and accessories)	Bipolar endoscopic coagulator-cutter and accessories
Indications for Use	The LiNA Bipolar Loop is a 5mm bipolar electrosurgical device intended for amputating the mobilized uterus during laparoscopic supracervical (subtotal) hysterectomy and resection of devasculated subserosal pedunculated myomas. To be used with an electrosurgical generator that provides a bipolar outlet.	The LiNA Loop is a 5mm monopolar electrosurgical device intended for sectoring the mobilized uterus during Laparoscopic supracervical hysterectomy. To be used with an electrosurgical generator	The PKS BILL is a 5mm bipolar electrosurgical device intended for sectoring the mobilized uterus during Laparoscopic supracervical hysterectomy and the resection of devasculated subserosal pedunculated myomas. Working in conjunction with Gyrus ACMI generator
Material	1. Gold plated stainless steel wire with molded zirconia ceramic tip and	1. Stainless steel wire	According to PKS BILL 510(k), K111059 summary "Uses materials that are well

Manufacturer	**LiNA Medical ApS** Formervangen 5 2600 Glostrup Denmark	**LiNA Medical ApS** Formervangen 5 2600 Glostrup Denmark	**Gyrus ACMI, Inc** 136 Turnpike Rd. Southborough, MA 01772-2104
Trade Name	LiNA Bipolar Loop	LiNA Loop	PKS BiLL
	polyamide cap. 2. Shrink tube: FEP (Teflon) 3. Funnel: Black polyamide 4. Cannula/Fibre tube: Vinyl ether resin with fiberglass reinforcement 5. Inner cannula Tube: Kynar® 6. Handle: ABS 7. Cable: Thermoplastic polyurethane with brass connector.	2. Shrink tube: Kynar®(PVDF) 3. Funnel: Black polyamide 4. Fibre tube: Vinyl ether resin with fiberglass reinforcement 5. Inner cannula Tube: Kynar® 6. Handle: ABS 7. Cable: PVC with brass connector.	established".
Sterile	Sterile packed. Ethylene Oxide Gas SAL 10^{-6}	Sterile packed. Ethylene Oxide Gas SAL 10^{-6}	Sterile packed. Gamma Irradiation. SAL 10^{-6}
Single-Use	Intended for single use only.	Intended for single use only.	Intended for single use only.
Shelf Life	3 years	3 years	Unknown
Battery Operated	N/A	N/A	N/A
AC Powered	N/A	N/A	N/A
Complies with ISO 10993-1	Yes	Yes	Yes
Electrical Safety Testing Passed	IEC 60601	IEC 60601	IEC 60601

9. Non-Clinical Performance Data

The following testing has been performed to support substantial equivalence:

- Efficacy and Functionality Test – The LiNA Loop and the LiNA Bipolar Loop had similar cutting quality in simulated tissue study using pork and beef muscle. Cutting quality was assessed on a scale of 1-9, with 5 being the acceptance criteria. 200mm sized loops were selected as this represented the mid-size loop for both the Bipolar Loop and Loop. The loops were assessed for cutting quality at high and low power settings. Both devices were qualitatively scored as a 5. Furthermore, cutting time was assessed, with an average deviation time between cuts of 0.85 seconds. Cutting time was assessed at the respective high and low power settings using three different generators and found to be within acceptable limits (±4 seconds). Therefore, the cutting time and quality were equivalent between the LiNA Loop and the LiNA Bipolar Loop.

As part of demonstrating the safety and effectiveness of the LiNA Bipolar Loop and in showing substantial equivalence the predicate devices that are subject to this 510(k) submission, LiNA Medical ApS completed a number of tests. The LiNA Bipolar Loop meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications. The LiNA Bipolar Loop passed all testing stated above as shown by the acceptable results obtained.

The LiNA Bipolar Loop complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the LiNA Bipolar Loop and the predicate devices do not raise any questions regarding its safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the LiNA Bipolar Loop is substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. The LiNA Bipolar Loop, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2013

LiNA Medical ApS
% Richard Gillis, Ph.D.
Senior Regulatory Consultant
Emergo Group, Inc.
611 West 5th Street, Third Floor
Austin, TX 78701

Re: K130305
Trade/Device Name: LiNA Bipolar Loop
Regulation Number: 21 CFR 884.4150
Regulation Name: Bipolar endoscopic coagulator-cutter and accessories
Regulatory Class: Class II
Product Code: HIN
Dated: June 07, 2013
Received: June 10, 2013

Dear Richard Gillis, Ph.D.,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number (if known): ~~Not Assigned~~ K130305

Device Name: LiNA Bipolar Loop

Indications for Use:

The LiNA Bipolar Loop is a 5mm bipolar electrosurgical device intended for amputating the mobilized uterus during laparoscopic supracervical (subtotal) hysterectomy and resection of devasculated subserosal pedunculated myomas. To be used with an electrosurgical generator that provides a bipolar outlet.

Prescription Use__x__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

K130305